BISMICS Consensus Statement: Implementing a safe minimally invasive mitral programme in the UK healthcare setting

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List of abbreviations

AoX	Aortic cross clamp
EABO	Endoaortic balloon occlusion
LOS	Length of stay
Mini-MVS	Minimally invasive mitral surgery
TOE	Trans oesophageal echocardiography
TTC	Transthoracic clamp
VATS	Video assisted thoracoscopic surgery

1 Abstract

Disseminating the practice of minimally invasive mitral surgery (mini-MVS) can be challenging, despite its original case reports a few decades ago. The penetration of this technology into clinical practice has been limited to centres of excellence and mitral surgery in most general cardiothoracic centres remains to be conducted via sternotomy access as a first line. The process for the uptake of mini-MVS requires clearer guidance and standardisation for the processes involved in its implementation.

In this statement, a consensus agreement is outlined that describes the benefits of mini-MVS, including reduced post-operative bleeding, reduced wound infection, enhanced recovery and patient satisfaction. Technical considerations require specific attention and can introduced through simulation and/or use in conventional cases. Either endoballoon or aortic cross clamping are both recommended as well as femoral or central aortic cannulation, with the use of appropriate adjuncts and instruments.

A coordinated team-based approach that encourages ownership of the programme by the team members is critical. A designated proctor is also recommended. The organisation of structured training and simulation, as well as planning the initial cases are important steps to consider.

The importance of pre-empting complications and dealing with adverse events are described, including re-exploration, conversion to sternotomy, uni-lateral pulmonary oedema and phrenic nerve injury. Accounting for both institutional and team

considerations can effectively facilitate the introduction of a mini-MVS service. This involves simulation, team-based training, visits to specialist centres and involvement of a designated proctor to oversee the initial cases.

2 Introduction

In the current era of surgeon-specific outcome publication, cardiac surgery in the NHS has adopted a culture of evolutionary practice as opposed to revolutionary progression(1). The process of introducing new technologies and procedures is multifaceted, underpinned by the demonstration of both patient safety as well as clinical effectiveness. The innovation of techniques in minimally access mitral surgery (mini-MVS) has dominated the cardiothoracic community for the last 2 decades. Despite this, the penetration of this technology into clinical practice has been limited to centres of excellence and mitral surgery in most general cardiothoracic centres remains to be conducted via sternotomy access as a first line. When compared to the conventional sternotomy approach, the procedure has implications for the surgeon, surgical team and post-operative healthcare staff with regards to surgical equipment, perioperative parameters and bedside adjuncts(2). These in turn requires a common agreement on the use of appropriate outcome metrics and benchmarking.

This consensus report will serve to comprehensively review the evidence for the practice of mini-MVS and use this to highlight the important considerations when initiating a new mini-MVS programme in a UK Healthcare Trust.

3 Evidence for minimally invasive mitral surgery

There are currently no adequately powered randomised controlled trial data comparing minimally invasive and conventional mitral valve surgery. However, Mini-MVS has shown to have benefits demonstrated through specific metrics as described below.

3.1 Reduced post-operative bleeding

One of the main worries of mini-MVS is the prospect for conversion to larger access owing to complications during surgery. However, mini-MVS has been found to reduce the need for re-exploration for bleeding compared to conventional sternotomy. Chitwood Jr and colleagues(3) conducted a meta-analysis with 1553 participants showing reduced need for reoperation for bleeding with mini-MVS. Studies as early as 20 years ago also supported this notion reporting 1.8 units fewer red blood cell transfusion in patients undergoing mini-MVS compared to conventional sternotomy(4,5).

3.2 Wound sepsis

A smaller area of disruption in skin integrity allows for less inoculation with commensal microbes, especially in patients with diabetes, immunosuppression and higher body mass index. In an observational study conducted by Grossi *et al.* (5), the rates of septic wound complication in adult were 5.7% and 0.9% (p=0.05) in median sternotomy and mini-MVS groups, respectively. This benefit also continued to be evident in elderly patients(6).

3.3 Patient satisfaction (shorten)

Mini-MVS is associated with less postoperative pain and quicker return to normal activity. This translates to an improved quality of life in the early post-operative period(7). Glower et al.(8) showed that patients found that pain resolved more quickly and were able to return to activities of daily living up to 5 weeks earlier after mini-MVS compared to median sternotomy, perhaps a result of improved stabilisation of the thorax (3,4). Furthermore, several studies have reported a demonstrable cost saving with mini-MVS which could be a result of shorter length of stay (LOS)(9–11).

3.4 Benefits in redo surgery

Redo cardiac surgery is traditionally performed through a repeat median sternotomy. However, this procedure is technically challenging due to dense adhesions and has a considerable risk of injuries to cardiac and vascular structures, which are independent risk factors for mortality(12). In 2018, a meta-analysis with a total of 777 patients demonstrated mini-MVS as a valid alternative in redo MVS with significantly reduced rates in mortality, LOS and reoperation for bleeding(13).

4 Training and learning curve

Cautious management of the learning curve in surgical procedures can be a predictor of success(14)(15). Notably, the effect of learning curve on patient outcomes does not rely on individual surgeon's experience but the entire operative team (16).

Monitoring the institution's progress through the learning curve is important. Cumulative sum (CUSUM) is a method to analyse a learning curve for a surgical team, variability within surgeons and to predict the number of cases required in order to overcome the learning curve(17). A study using CUSUM analysis in 3895 mini-MVS cases identified that adverse events (e.g. conversion to sternotomy, re-exploration, stroke) reduced to the normal range of 10% after 250 cases(18). In addition, greater than 50 cases per annum are required to maintain most the favourable results, amounting to an optimal procedure rate of one per week.

Yaffee *et al*(19) demonstrated significantly shorter learning curves for totally endoscopic robotic mitral valve repair as a result of focused training in both technical and non-technical skills. Comparatively, appropriate training in minimally invasive aortic valve replacement (mini-AVR) has also been possible without compromising patient safety(20), although the use of sutureless technology can aid with its learning curve(21) (an option not available for mini-MVS).

Devising a specific training programme or fellowship in a large volume centre will allow surgical proficiency to be reached in a timely fashion, thus facilitating the uptake of mini-MVS into the healthcare system more readily. Mentorship can be organised through the provision of dedicated fellowships and mentor schemes, which can be uniquely facilitated via specialist societies, such as British and Irish Society of Minimally Invasive Cardiac Surgery (BISMICS) and Society of Cardiothoracic Surgeons of Great Britain & Ireland (SCTS). This can allow for targeted training of cardiac surgeons to promote the development of minimally invasive cardiac surgeons. Industry partners may play an important role in supporting proctors and surgeons.

5 Technical challenges to overcome

Mini-MVS is a technically demanding complex procedure. Considerations for new learning curves have been proposed in mini-MVS, namely altered incisions, reduced operative space, endoscopic instrumentation, and aortic occlusion(22). The recommendations from this consensus statement are summarised in Table 1.

5.1 Mitral valve repair

Surgeons should be comfortable with the techniques of repair by operating on an adequate number of sternotomy access mitral procedures. The build up to mini-MVS should also be graduated, ensuring that the twenty initial cases are straightforward, commonly P2 prolapse cases, which could be considered the simplest mitral procedure.

5.2 Incision size

The goal of a thoracotomy incision is to make it less than 5cm in length which has numerous patient benefits. For the initial cases, the skin incision can be made slightly longer to assist visualisation as it is the avoidance of sternotomy or no rib-spreading which provides clinical benefit. Beyond this, the relationship between volume and outcome remains true in mini-MVS, and it would not be unreasonable that the time to be considered an expert in mini-MVS may take a few years. Overcoming the challenges of operating in a reduced space is perhaps the largest challenge for the surgeon.

5.3 Aortic occlusion

Aortic occlusion is achieved currently by 2 techniques available to surgeons: i) transthoracic clamp (TTC); and ii) endoaortic balloon occlusion (EABO). The TTC technique is simpler and involves inserting a clamp through the intercostal spaces to clamp the ascending aorta. The EABO technique is associated with a longer learning curve as the procedure requires more monitoring and experience. It involves accessing the aorta through a catheter inserted either in the femoral artery or directly through the ascending aorta with an inflatable balloon at its tip. This is guided by TOE, the balloon is inflated and the aorta occluded. In a recent meta-analysis, the only advantage of TTC over EAOB was the reduction in aortic dissection complications [risk ratio 0.33, 95% confidence interval (CI) 0.12-0.93; P = 0.04](23).

The use of aortic occlusion method currently remains entirely down to surgical preference and newer adjuncts for aortic occlusion are yet to penetrate surgical practice. Importantly, occluding the aorta through AXT or EABO is a learning curve that the surgeons can only ascend during minimally invasive procedures. A useful option for TOE-guided cannulation, would be gaining the patient’s consent to practise percutaneous femoral cannulation on sternotomy or hemi-sternotomy cases could be a viable method for improving the surgeon’s familiarity with this alternative strategy.

5.4 Endoscopic mini-MVS

Thoracoscopes have been implemented in mini mitral surgery for over two decades helping to reduce complications via improved visualisation(24), although familiarity for their use is required and mainly specialised centres advocate performing mini-MVS totally endoscopically(25). In 2008, Chitwood and colleagues described levels of minimally invasive mitral surgery based on the size of the incisions and progressive use of video assisted or robotic assisted surgery(26) (Table 2).

Robotic assisted mini-MVS techniques, although safe and effective, are associated with more difficult learning curves. Robotic surgery provides ergonomic gains which improve the surgical process and the smaller incision sizes are favoured by patients. Current evidence is mostly based on observational studies, and therefore randomised trials may be required in order to definitively assess the advantages and disadvantages of these techniques(27).

6 Implementing the first few cases

6.1 Early engagement with hospital and patients

In most hospitals, all new procedures need prior approval from a hospital committee, which has ethical, cost, patient outcome and management considerations. This ensures patient safety, highlights clinical governance and maintains quality control. The hospital committee may have a specific application process and ask for prerequisite information prior to issuing favourable support. Usually, this involves description and indications of the proposed procedure, intended benefits, possible complications, summary of evidence base, estimated number of annual procedures to be performed and names of supporting colleagues(28).

Evidence suggests that patients prefer detailed explanations of their treatment and decisions made surrounding it(29,30). Written material explaining why the department is employing the new procedure, evidence surrounding its use, as well as what patients should expect following the procedure should be offered containing visual aids and diagrams. Risks of mini-MVS should be explained openly and helps avoid confusion or anxiety.

6.2 Selecting the initial cases

In the initial period (first 20 cases), appropriate patient selection is key. This ensures patient safety and allows the surgeon and team to “break in” to the novel procedure with as minimal complications as possible. In the early stages, should avoid:

1. very elderly,
2. grossly obese,
3. current smokers
4. high-risk (high Euroscore).
5. complex repairs (stick to straightforward annuloplasty +/- P2 resection)

In actual fact, it is these very patients who may benefit from mini-MVS the most(31,32). However, in the initial stages of implementation, the complication rate may be higher.

Other contraindications to mini-MVS that would persist beyond the initial cases should also be described and made clear in the institution’s protocol. Although not absolute contraindications, each patient should be considered on an individual basis via a risk-benefit analysis and through the consideration of the multi-disciplinary process. The contraindications to be considered have been outlined in Table 3.

6.3 Equipment needs

An important recommendation for familiarisation with mini-MVS technology is to make use of them during established open procedures. This includes the thoracoscope, knot pusher and TOE-guided cannulation (Table 4). Space will be less restricted and safety for their use in these scenarios would not be compromised. Local departmental teaching attended by all involved personnel and team members from different specialties should also be delivered. This allows for the following opportunities:

1. Invited speakers from specialised centres or equipment companies
2. Watching operative videos of the procedure
3. Exploring the rationale of the new technology
4. Group discussion
5. Handling of specialised instruments and discussion surrounding their use
6. Agree to one case per day for the whole team to allow adequate time for a full de-brief where each member of the team has a voice

6.4 Trainees and surgical assistants

Establishing the new service should have a long-term vision that includes transferring the knowledge and skills to junior colleagues who can lead and participate in the service in subsequent years. Including trainees in visits to specialised centres, teaching sessions and group discussions surrounding the new procedure should be encouraged. Assisting in the initial cases is also recommended.

The use of high fidelity virtual reality simulation training has demonstrated benefit in many fields of minimally invasive surgery(33–35) including thoracoscopic surgery. This helps shorten the learning curve outside the operating theatre and hence improve patient safety whilst new procedures are being implemented.

6.5 Staff considerations

The importance of team concordance and communication surrounding these new process entities are paramount. In this light, the need for simulation is highly recommended. Scheduling a visit to a customised simulation centre with specialised assessment equipment and simulated theatres is extremely useful. Specialised audio-visual equipment can allow for unique playback and feedback opportunities to allow team members to improve on personal aspects of communication. Promoting positive relations and trust between the team members play an important role in ensuring the efficient running of complex procedures. Studies in many surgical specialties have shown that the familiarity of team members is key to minimising operative related complications, reduce operative time and improve patient outcomes(36,37).

Devising 1-2 mini mitral specific checklists is also highly recommended. This will help reduce untoward error related to equipment, staff, or theatre processes. This may be used to benefit specific staff, or groups of staff, members, for example scrub nurses when checking equipment preparation and theatre ODPs when checking theatre and patient readiness.

It is important to note that initiating a novel mini-MVS service has significant benefits for the institution. For the staff, this can be a catalyst for improving team morale, self-belief and skill progression. Becoming a unit that collectively leads in the implementation of new technology and techniques will carry both staff and patient benefit.

7 Dealing with adverse events

Establishing a culture of objectivity is critical for the audit process. This involves the leading members of the service and team promoting an ethos of openness, honesty and devoid of blame. Moving to a Mini-MVS approach does expose the surgeon and his team to a different set of complications related to alternative cannulation strategies and new incisions. All adverse outcomes need to be clearly documented and each can be virtually eliminated by constant improvements in both technique and technology used. Regular conversations with a mentoring surgeon or team helps understand specific complications and leads to a lower incidence.

7.1 Bleeding and re-exploration

One of the underlying causes of conversion from mini-MVS to median sternotomy is bleeding(49), although literature has shown that mini-MVS leads to a reduction in bleeding and re-exploration compared to sternotomy(38). Management of post-operative bleeding should adhere to strict standards as with other cardiac surgical procedures. The need for adequate surgical re-exploration for severe haemorrhage should not be overshadowed by the desire to maintain the integrity of minimal access(38). In the first instance, hypothermia and acidosis should be closely monitored, and crystalloid administration should be minimised to avoid haemodilution(39). Additionally, excessive hypertension should be avoided, and mean arterial pressure levels should not be allowed to run higher than 90mmHg(40) and timely transfusion with blood products is required(41).

Dense pulmonary adhesions are another cause of conversion to sternotomy. This is associated with patients with a background of pulmonary diseases(42). Hence, a detailed pre-operative computerised tomography (CT) scan with anatomical consideration and detailed MDT discussion should be carried out in these patients.

7.2 Pulmonary oedema

There have been reports of unilateral pulmonary oedema (a rare but life-threatening complication) occurring after mini-MVS(43), with the pathophysiology thought to be inflammatory related. The cause-effect relationship is yet to be established, as many cases of severe pulmonary oedema can also be observed following sternotomy access for cardiac procedures. Two landmark trials found a role for peri-operative intravenous steroids in sternotomy cardiac patients for the significant reduction in the incidence of pulmonary oedema(44,45) although this has not been formerly trialled in mini-MVS. Retrospective studies in mini-MVS have found that the introduction of peri-operative steroids in mini-MVS may lead to a reduced incidence of clinical and radiological pulmonary oedema(46). Careful ventilatory strategies may also need to be employed to reduced volu- and barotrauma related lung injury(47).

7.3 Phrenic nerve palsy

The risk of phrenic nerve palsy with mini-MVS has been reported to increase by 3% compared to conventional sternotomy(38). This can have adverse implications as patients may experience respiratory distress and prolonged ventilation(48). It is speculated phrenic nerve palsy results from excessive pull on pericardial traction sutures which are used for better visualisation of the left atrium(48). Therefore, measures to incise the pericardium further away from the phrenic nerve (preferably >3 cm) and avoid retraction sutures near the nerve to prevent extensive pull(3) are advocated. It is important to note that phrenic injury is an avoidable complication, which gives emphasis to the importance of rigorous attention to this part of the procedure when training surgeons in mini-MVS.

7.4 Pain

Although Mini-MVS confers a smaller incision, chronic pain can develop as a result of intercostal nerve damage(49). Randomised control studies are lacking in this area, although the use of various analgesic techniques have been reported. The use of a catheter inserted in close proximity to intercostal space before skin closure with administration of 75 mg of 0.75% ropivacaine has been shown to eliminate early post-operative pain(49). Alternatively, intercostal nerve blockade combined with general anaesthesia has also been reported(50) achieved by the administration of 0.5% ropivacaine from T3 to T7 prior to anaesthesia induction. Intractable cases of chronic pain secondary to intercostal nerve traction is likely to require input from neuropathic pain specialists to employ patient specific therapy. Most cases of pain tend to resolve within 12 months, and many lessons can be drawn from thoracic surgical practice whose patients frequently have pain related to the intercostal nerve.

8 Conclusion

This consensus statement has outlined the important considerations and processes for establishing a workable, effective and sustainable mini-MVS service in a modern UK healthcare system. The aim of the authors is to promote standardised practice to allow the effective and safe dissemination of novel technology in healthcare for the betterment of patients requiring mitral surgery.

Contributorship Statements

Hunaid A Vohra: conception, writing, proof-reading (guarantor)

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Competing interests

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Table 1: Summary of recommendations for mini-MVS

Patient selection
1. Patients with degenerative MR may be considered for minimally invasive mitral surgery with comparable outcomes to full sternotomy.
2. Patients who have had previous cardiac surgery and require intervention on the mitral valve can be considered for minimally invasive mitral surgery.
3. In the initial stages of implementing a mini-mitral service, low risk patients should be selected who also have a lower chance of complications (non-smokers, low BMI, non-diabetic, P2 prolapse).
Cardio-pulmonary Bypass
4. The use of either an endo-aortic balloon or external cross clamp are recommended during minimal access mitral surgery, with little evidence of one preference over the other.
5. Femoral or direct aortic cannulation are both acceptable strategies to institute cardio-pulmonary bypass.
6. The use of TOE guidance for arterial and venous cannula positioning during the institution of cardiopulmonary bypass is highly recommended.
Staff/Governance
7. The use of simulation with the surgical team prior to conducting the first live case of minimal access mitral surgery is highly recommended.
8. The implementation of a “dry run” in the unit’s theatre using the relevant equipment and staff is recommended.
9. Regular audit of initial mini mitral cases at a surgical unit, and subsequent mini mitral cases is highly recommended

Table 2: Levels of minimally invasive cardiac surgery. Adapted from Chitwood et al 1997 (9)

Level 1	Direct vision: (10–15 cm incisions)
Level 2	Direct vision/video assisted with mini incisions (4–6 cm)
Level 3	Video directed and robot assisted with micro incisions (1.5–4 cm)
Level 4	Robotic (computer telemanipulation) and totally endoscopic port incisions (< 1.5 cm)

Table 3 Contraindications for minimal access mitral surgery

Contraindication	Implications for mini mitral surgery	Methods to circumvent
Prior right chest surgery or radiation	Patients are at increased risk due to pleural adhesions	Preoperative CT scan can allow for operative planning with specific adjuncts and techniques to avoid damage to major structure (50,51)
Severe peripheral atherosclerosis or chronic peripheral arterial occlusive disease. Descending aorta aneurysm, aortic dissection, aortic thrombus	Peripheral cannulation for CPB can be particularly challenging for these patients	Alternate routes of CPB to be considered or full sternotomy
Prominent ascending aorta calcifications or ascending aorta aneurysm/dilation (> 4.5 cm)	Aortic clamping and antegrade cardioplegia administration are challenging in these patients.	Consider endo-balloon or percutaneous mitral valve repair
Moderate to severe aortic regurgitation (AR)	Difficulties with cardioplegia administration	Conventional sternotomy
Significant chest wall deformity (particularly severe pectus excavatum)	Challenging access to all intra-thoracic structures	Conventional sternotomy
Severe mitral annular calcification.	Extensive decalcification of the mitral annulus and reconstruction with a pericardial patch is very challenging through a minimal invasive approach	Conventional sternotomy or Percutaneous mitral valve replacement

Table 4 Technical aspects of minimal access mitral surgery and relevant ways to introduce into a new unit

	Attempts on sternotomy mitral cases	Wetlab	Team based simulation	Visit to specialist centre	Visit from proctor to unit
Mini thoracotomy		√		√	√
TOE guided aortic cannulation	√		√	√	√
Aortic occlusion				√	√
Knot pushing	√	√	√	√	√
Thoracoscopic adjunct	√			√	√